

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/706,405	SHINOKI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeanine A Goldberg	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/3/00; 12/6/02.
  2. ☒ The allowed claim(s) is/are 1 and 3-10.
  3. ☒ The drawings filed on 03 November 2000 are accepted by the Examiner.
  4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
    - (a) ☐ The translation of the foreign language provisional application has been received.
  6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.            |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____.              | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                  |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
|  | 9 <input type="checkbox"/> Other  |

**Detailed Action**

1. This action is in response to the papers filed December 6, 2002.

***Election/Restrictions***

2. Applicant's election without traverse of Group I (Claims 1, 3-10) in Paper filed December 6, 2002 is acknowledged.

***Priority***

3. This application claims priority to foreign application Japan 11-314915, filed November 5, 1999.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

***Drawings***

4. The drawings are acceptable.

**EXAMINER'S AMENDMENT**

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

6. Authorization for this examiner's amendment was given in a telephone interview with Jules Goldberg on May 28, 2003.

7. The application has been amended as follows:

A) 1. (Twice Amended) A method for fixing a plurality of nucleotide derivatives to a solid carrier comprising:

contacting aqueous phase nucleotide derivatives each having a reactive group at one terminal with a solid carrier having thereon reactive groups in the presence of a transferase ,

wherein the transferase produces a covalent bond by rearrangement of the reactive group of each nucleotide derivative and the reactive groups of the solid carrier thereby fixing the plurality of nucleotide derivatives to a solid carrier;

wherein the nucleotide derivatives are selected from the group consisting of oligonucleotides, polynucleotides and peptide-nucleic acids.

B) This application is in condition for allowance except for the presence of claims 11-12 to a solid carrier and a process of fixing nucleic acid fragments non-elected without traverse. Accordingly, claims 11-12 have been cancelled.

8. The following is an examiner's statement of reasons for allowance.

The claims are drawn to a method for fixing a plurality of nucleic acids to a solid carrier using a transferase.

The art teaches transferase is one of six categories of enzymes. The six main classes of enzymes include 1) oxidoreductases 2) transferases, 3) hydrolases 4) lyases 5) isomerases, and 6) ligases or synthases. Therefore the claims do not encompass the use of enzymes such as ligases to attach the nucleic acid to a solid support.

The specification teaches transferases include carboxyl transferase, carbamoyl transferase, aminoacyl transferase, amide transferase, ornithine transferase, transglutaminase, aspartyl transferase and D-glutamyl transferease (page 8 of the Specification). The specific example provided in the specification teaches using D-glutamyl transferase as the enzyme for attaching the nucleic acids to the solid support. Further the art teaches that glutamine transaminase and hexokinase are transferases.

The prior art also teaches the use of terminal transferases for labeling of DNA (see for example US Pat. 6,344,316- Lockhart). Lockhart et al teaches that the end labeling can be accomplished by providing a nucleic acid, providing labeled nucleoside triphosphates, and attaching the nucleoside triphosphates to the nucleic acid using a terminal transferase.

Additionally, the prior art teaches addition of nucleotide residues to the fragment with terminal transferase (see for example US Pat. 5,403,711- Walder). This teaching is directed to after the support material is prepared by the procedures, the attached oligonucleotide may be extended to yield longer nucleotide sequences. The passage directed to terminal transferases specifically states, "suitable procedures include, but are not limited to, addition of nucleotide residues to the fragment with DNA polymerase or terminal transferase, and ligation of polynucleotides to the initial sequence attached

to the support using DNA or RNA ligase" (col. 14, lines 27-32). The instant claims are drawn to addition of oligonucleotides, polynucleotides and PNAs which are larger than a single residue. The teachings of Walder would not suggest to the ordinary artisan that terminal transferases could be used to extend immobilized oligonucleotides by more than one residue. The passage of Walder specifically provides that multiple residues, i.e. polynucleotides, may be added to the support using ligation. Therefore, there is no motivation to add polynucleotides using a terminal transferase since the reference has already addressed the addition of polynucleotides and suggested using ligation. Therefore, the teachings of Walder fail to suggest the addition of polynucleotides to a solid support using a transferase as required by the instant claims.

The prior art also teaches attaching microscopic bead or other structures to nucleic acids using a terminal transferase (see US Pat. 6,420,112- Balhorn). The method taught by Balhorn is directed to a method which uses a terminal transferase in a DNA solution to add a labeled base to each end of the DNA strand, and then mix the labeled DNA with beads. Unlike the instantly claimed invention, the oligonucleotides are not attached to the solid support via a transferease. The terminal transferase is used to add a single labeled dideoxy nucleotide base to both ends of DNA. The labels are then bound to the solid support. Therefore, the teachings of Balhorn fail to meet the instant claims for several reasons. Balhorn does not teach contacting aqueous phase oligonucleotides with a solid carrier in the presence of a transferase. Rather Balhorn teaches using a single nucleotide residue. Moreover, the covalent bond occurs between the bead and ligand rather than a bond produced by a transferase.

Therefore, the art neither teaches nor suggests the claimed invention as a whole.


Therefore, the claims are allowable over the art.


9. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Jeanine Goldberg  
May 29, 2003

  
GARY BENZION, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600